

# Notice of Allowability

Application No.

09/913,970

Examiner

Daniel M. Sullivan

Applicant(s)

MARKHAM ET AL.

Art Unit

1636

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Paper filed 28 July 2006.
2. ☒ The allowed claim(s) is/are 1,4,7,29 and 47.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Daniel M Sullivan, Ph.D.  
Primary Examiner  
Art Unit: 1636

### EXAMINER'S AMENDMENT

#### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 July 2006 has been entered.

#### *Election/Restrictions*

Claims 1 and 7, as amended herein below, are allowable. The restriction requirement among inventions I-VI, as set forth in the Office action mailed on 19 March 2004, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 25-27, 31-33 and 37, directed to methods of using or pharmaceutical compositions comprising the elected invention are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Art Unit: 1636

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shawna Cannon Lemon, Reg. No. 53,888 on 28 September 2006.

The application has been amended as follows:

**In the claims:**

Claims 25-27, 31-33 and 37 are canceled.

1. (Currently Amended) An isolated nucleic acid encoding a latency promoter, wherein the latency promoter is operatively linked to a heterologous gene and drives expression of said heterologous gene in human cells, and wherein the latency promoter ~~is encoded by~~ comprises at least 630 bp of nucleotides ~~4-633-1362-2000~~ of SEQ ID NO: 1 and up to 2000 bp of nucleotides

Art Unit: 1636

~~4-2,003-2-2000~~ of SEQ ID NO: 1 ~~of a nucleic acid sequence immediately upstream of an initiation codon of open reading frame (ORF) 73 of HVS, as set forth in SEQ ID NO:1.~~

7. (Currently Amended) A recombinant DNA molecule comprising at least one insert that encodes a latency promoter operatively linked to a heterologous gene and ~~that~~ drives expression of ~~a~~ said heterologous gene in human cells, wherein the latency promoter comprises at least 630 bp and up to 2000 bp of ~~a~~ the nucleic acid sequence immediately upstream of ~~an~~ the initiation codon of ~~open reading frame (ORF) 73~~ ORF73 of HVS, as set forth in SEQ ID NO:1.

29. (Currently Amended) The recombinant DNA molecule according to Claim 7, wherein said latency promoter ~~is encoded by~~ comprises a nucleic acid sequence of up to a length no greater than 630 bp of SEQ ID NO: 1.

47. (Currently Amended) An isolated nucleic acid encoding a latency promoter, wherein said latency promoter is operatively linked to a heterologous gene and drives expression of said heterologous gene in human cells, and wherein said isolated nucleic acid comprises nucleotides ~~4-20032-2000~~ of SEQ ID NO:1 ~~and said isolated nucleic acid is located immediately upstream of the initiation codon of open reading frame (ORF) 73 of HVS as set forth in SEQ ID NO:1.~~

Support for the instant amendments to the claims is found in the specification as filed. In particular, the specification contemplates at page 17, first full paragraph, the size ranges recited

Art Unit: 1636

in the claims. Furthermore, in the paragraph bridging pages 13-14, the application teaches isolation of portions of the ORF73 sequence using primer pairs that would amplify nucleotides 1362-2000 (SEQ ID NO: 8 + SEQ ID NO: 9) and 2-2000 (SEQ ID NO: 12 + SEQ ID NO: 13) of SEQ ID NO: 1. Thus, the disclosure provides implicit support for the fragments recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.

Primary Examiner

Art Unit 1636